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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/066,057 | 01/31/2002 | Michael B. Zemel | UTR-104D1 | 8306 |

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| EXAMINER | |
|---|---|
| WEBMAN, EDWARD J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1616 | |

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/066,057 | ZEMEL ET AL. | |
| | Examiner | Art Unit | |
| | Edward J. Webman | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,5,6 and 27-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6 and 27-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1, 5, 6, 27-64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for those on a low-calorie diet and who are not already consuming three servings of dairy, does not reasonably provide enablement for on any diet and consuming any amount of dairy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The "Express," a daily tabloid published by the Washington Post, is cited as extrinsic evidence containing an admission by one of the inventors, Michael Zemel. In an article on page 10 of the 7/19/ 05 issue he is cited as stating that the claimed invention works only for people who eat a low-calorie diet and who are not already consuming three servings of dairy. Applicants' claims do not recite such limitations. Applicants are advised that such an amendment to the claims must be supported by the specification.

Applicants continue to argue the interview is not admissible because it is hearsay. However, applicants provide no authority for their premise.

Applicants cite the Federal Rules of Evidence for their authority. However, applicants are silent as to whether there is a requirement in the MPEP that the USPTO follow these rules. Applicant questions the authority for characterizing the reported statement of the inventor as an admission., having found that the issue as to whether the inventor's reported statements constitute an admission do not appear to be addressed in the MPEP. Given that the issue does not appear to be addressed in the MPEP the examiner relies on the ordinary meaning of the term, namely, an admission is

a concession, acknowledgement or confession. The reported statements of the inventor, in the context of the current prosecution, is characterized as a concession.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 6, 27-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Metz et al (AJH 1:58-60 1988).

Metz et al teach a reduction in body fat content in rats consuming higher diets of calcium (abstract). An inverse relationship between dietary calcium and body weight is disclosed (page 59 first sentence under the subsection "Weight" in the section entitled "RESULTS").

It would have been obvious to one of ordinary skill to formulate a high calcium diet for humans to achieve the beneficial effect of a reduction in weight in view of the Metz et al results.

As to the particular claimed dosage frequency, amount, and vehicle, optimum parameters may be obtained by routine experimentation. In re Boesch 205 USPQ 215 (CCPA 1980). Regarding the alternative increase in metabolic consumption of adipose tissue in claim 51, one of ordinary skill will recognize that reduction in body fat content is a consequence of lipolysis of fat in adipocytes. As to the particular claimed foods, they

are well known to contain calcium. As to the claimed supplements, such are also well known, even to the layman.

Applicant argues that Metz et al teaches both calcium and sodium ions. However, applicants do not exclude sodium. Applicant argues unexpected results. However, Metz et al, prior to applicant's effective date, disclose applicant's invention. Applicant argues extensive experimentation, however, applicants do not demonstrate that the dosages are critical or that the experimentation to determine them was not routine. Applicants object to the examiner taking notice regarding documentation. As to the statement that a reduction in body fat content is a consequence of lipolysis of fat in adipocytes, the examiner cites US 6,716,810 column 17 lines 29-48, wherein the inventors refer to fat stores metabolized from peripheral adipose tissue by stimulation of lipolysis from adipocytes. As to the fact that the claimed foods are well known to contain calcium the examiner refers to Table 2 from the NIH fact sheet on calcium available on the internet.

Claims 1, 5, 6, 27-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skinner et al (Scand J Nutr 2/99 suppl 34 p. 45S).

Skinner et al teach that children's fat mass is moderated by dietary calcium (abstract).

It would have been obvious to one of ordinary skill to formulate a high calcium diet for children to achieve the beneficial effect of a reduction in body fat content in view of the Skinner et al.

As to the particular claimed dosage frequency, amount, and vehicle, optimum parameters may be obtained by routine experimentation. In re Boesch 205 USPQ 215 (CCPA 1980). As to the particular claimed foods, they are well known to contain calcium. As to the claimed supplements, such are also well known, even to the layman.

Applicant argues that Skinner et al does not concern calcium alone nor did the study concern weight loss. However, regarding variants other than calcium leading to the results in Sinner et al, applicants do not exclude them. As to the Skinner et al study of fast mass rather than weight loss, the calculation of fat mass is from the body mass index (BMI) of subjects, for which the correlation is significant. That is, decreases in fat mass correlate with a decrease in BMI. Applicant argues that energy was not restricted in the Skinner et al study. However, had it been restricted, the results would have been more pronounced. Applicant argues unexpected results, however, the Skinner et al teaching is prior to applicant's effective date. Applicant also objects to the examiner's reliance on determining applicant's dosage by routine experimentation and the examiner's taking of official notice, however, the examiner's response to these objections is incorporated herein from the rejection over Metz et al *supra* as it relates to Skinner et al.

Claims 1, 5, 6, 27-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Summerbell et al (BMJ 317 1998 p. 1487-89).

Summerbell et al teach weight loss in obese patients on a diet comprising milk or yoghurt (abstract, p. 1488 under "milk only").

It would have been obvious to one of ordinary skill to formulate a high calcium diet for obese patients to achieve the beneficial effect of a reduction in body fat content in view of the Summerbell et al.

As to the particular claimed dosage frequency, amount, and vehicle, optimum parameters may be obtained by routine experimentation. In re Boesch 205 USPQ 215 (CCPA 1980). As to the particular claimed non-dairy foods, they are well known to contain calcium. As to the claimed supplements, such are also well known, even to the layman.

Applicants argue that Summerbell et al teach away from a milk only diet, but rather diet rotation. However, that diet rotation would include the milk only diet or the theoretically superior milk plus diet. Applicants do not exclude diet rotation nor do they exclude a milk plus diet. Applicant also objects to the examiner's reliance on determining applicant's dosage by routine experimentation and the examiner's taking of official notice, however, the examiner's response to these objections is incorporated herein from the rejection over Metz et al *supra* as it relates to Summerbell et al.

Claims 1, 5, 6, 27-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 50, and 61 "restricted caloric diet below ad lib" is vague; the metes and bounds are unclear as to how far below ad lib. That is, what number of calories below ad lib must be maintained to achieve the claimed reduction in weight by ingestion of the claimed calcium dosage?

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor,, J. Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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